

Follow-on biologics and Medicare

ISSUE: Spending on high-priced biologics has been increasing rapidly, totaling over \$40 billion in 2007. Medicare pays for these drugs under both Part B and Part D but cannot achieve significant savings given the lack of a regulatory pathway for follow-on biologics.

KEY POINTS: For this presentation, we discuss the findings from an expert panel on follow-on biologics. Panelists included physicians, scientists, economists, health plan executives, attorneys, a scientist, experts on Medicare payments, and consultants to brand and generic pharmaceutical manufacturers. We discuss issues including:

- How to balance intellectual property rights with encouraging competition, and
- How to ensure product safety while determining product comparability.

We also look at how follow-on biologics might affect Medicare. Lastly, we look at strategies that consider clinical evidence in Medicare's rate-setting process to help the program become an astute purchaser of health care services.

ACTION: Commissioners should discuss issues raised by this research.

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